

HRV VX3+

Recorder

Manual

Series E



Caution: FEDERAL LAW RESTRICTS THIS DEVICE FOR SALE TO OR ON THE ORDER OF A PHYSICIAN.



Caution: Carefully read all instructions prior to use. Observe all warnings and precautions noted in these directions. Failure to do so may result in patient complications.

Table of Contents

Notices:

Conventions Used In This Manual.....	3
Manufacturer's Responsibility.....	3
User Responsibility.....	3
Equipment Identification.....	3
Copyright and Trademark Notices.....	3
Other Important Information.....	4

User safety information:

Intended Use.....	4
Explanation of Symbols.....	4
Warnings.....	5
Cautions.....	6
Notes.....	6

Section 1: Introduction

Purpose Of The User Manual.....	7
System Description.....	7
System Illustration.....	7 / 8

Section 2: Getting Started

Secure Digital Card.....	9
Battery.....	9
Screen Navigation.....	10
Selecting Features and Preferences	11
Start Up.....	11
Setup Menu.....	11
Set ID.....	11
Set Name.....	12
Pacemaker.....	12
Sample Rate.....	12
Record Length.....	12
Real Time Clock.....	13
Patient Cable.....	13
Patient Preparation.....	13
Patient Hookup.....	14 / 15

Section 3: Recording An ANS ECG

Data File Check.....	15
Event Button	15
Autonomic Nervous System Test Sequence	16
Data Retrieval.....	17
Recorder Messages.....	17

Section 4: Device Maintenance

Inspection and Cleaning.....	18
Battery Maintenance and Precautions.....	18
VX3+ Specifications	19
Service/Technical Support	19 / 20
Electromagnetic Emissions	21 / 22 / 23 / 24

Notices

Conventions Used in this Manual

WARNING:



Warning statements describe conditions or actions that can result in personal injury or loss of life.

CAUTION:



Caution statements describe conditions or actions that can result in damage to the equipment or loss of data.

NOTE:

Notes contain additional information on usage.

Manufacturer's Responsibility

CAIRD TECHNOLOGY INC. considers itself responsible for effects on safety and performance only if:

1. Readjustments, modifications or repairs to the CAIRD TECHNOLOGY INC. ANS recorders are carried out only by CAIRD TECHNOLOGY INC.-authorized personnel.

AND

2. The CAIRD TECHNOLOGY INC. VX3+ is used as presented in this manual.

The warranty is only valid if you use CAIRD TECHNOLOGY INC. -approved replacement parts and accessories.

User Responsibility

The user of this product is responsible for ensuring the implementation of a satisfactory maintenance schedule. Failure to do so may cause undue failure and possible health hazards.

Equipment Identification

CAIRD TECHNOLOGY INC. equipment is identified by a serial number on the back of the device. Please take care not to deface these numbers.

Copyright and Trademark Notices

This document contains information that is protected by copyright. All rights are reserved. No part of this document may be photocopied, reproduced or translated to another language without prior written consent of Caird Technology Inc.

Other Important Information

CAIRD TECHNOLOGY INC. reserves the right to change or amend this manual at anytime without notice. CAIRD TECHNOLOGY INC. makes no warranty of any kind with regard to this material, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose. CAIRD TECHNOLOGY INC. shall not be liable for errors or omissions that may appear in this document. CAIRD TECHNOLOGY INC. makes no commitment to update or to keep current the information contained in this document. Before using the CAIRD TECHNOLOGY INC. VX3+ ANS Recorder, read this manual in its entirety and become thoroughly familiar with the contents. *VX3+ User Manual Doc VZ-2080 rev. 0.3*

User Safety Information

Intended Use

The VX3+ ANS recorder is a small, portable, digital ANS recorder intended for use by medical professionals to acquire ECG data from a single patient in a clinical, point of care or outpatient setting. ECG data is first recorded to a Secure Digital (SD) card and then transferred to a ANS analysis system for review by a physician or other qualified professional.

Explanation of Symbols



READ MANUAL FIRST



KEEP AWAY FROM MOISTURE



TYPE BF DEVICE



DC CURRENT



ELECTRONIC EQUIPMENT
DISPOSE OF PROPERLY



MANUFACTURER / MANUFACTURE YEAR



Warnings

1. This device captures and presents data reflecting a patient's physiological condition that when reviewed by a trained medical professional can be useful in determining a diagnosis. However, the data should not be used as sole means for determining a patient's diagnosis.
2. Use of accessories other than those recommended by CAIRD TECHNOLOGY INC. may compromise product performance.
3. To maintain designed operator and patient safety, any peripheral equipment and accessories that can come in direct patient contact must be in compliance with IEC 601-1 and IEC 601-2-47.
4. Hardware is designed to meet or exceed IEC 601-1-2, however some environmental electrical interference may cause an artifact in the ECG. The quality of ECG signals may be adversely affected by electromagnetic interference from environmental sources resulting in non-physiological waveforms with the potential for misinterpretation.
5. This device is not intended for use during an MRI.
6. Before performing defibrillation or applying any high frequency surgical equipment to a patient, remove VX3+ leads and electrodes from the chest area. Cable leads or electrodes trapped under defibrillator pads or paddles during defibrillation or electrodes in contact with high frequency electrosurgical equipment can cause patient burns.
7. Once one or more VX3+ patient leads are connected to a patient, do not allow patient leads to meet with any grounded or live parts. Contact could cause unacceptable levels of electrical current to flow to the patient.



Cautions

1. To prevent possible damage to the keypad, do not use sharp or hard objects to depress keys.
2. Although the plastic enclosure is designed for a clinical environment and can resist moisture, neither the device nor patient cables should be cleaned by submersing into a liquid, autoclaving or steam cleaning. Wipe the exterior surfaces with a cloth dampened with warm water and mild detergent solution and then dry with a clean soft cloth.
3. No serviceable parts are inside. Only qualified service personnel may remove screws on the enclosure. The warranty is void if anyone other than qualified service personnel tampers with the device.
4. Do not pull or stretch patient cables, as this could result in mechanical and/or electrical failures. Store patient cables after use by forming them into a loose loop.
5. Align patient cable connector and VX3+ socket before plugging in patient cable. Forcing misaligned connectors can damage connector pins.
6. Avoid shock or sudden impact.

Notes:

1. Excessive patient movement could interfere with the operation of the device.
2. Proper patient preparation is important to successful application of ECG electrodes and operation of the device.

Section 1: Introduction

This manual is written for clinical professionals. It is assumed that the reader has a working knowledge of medical terminology and procedures as required for monitoring cardiac patients.

Purpose of the User Manual

The User Manual describes how to safely operate the VX3+ ANS recorder. In the manual, the following are described:

- Preparing the device for use
- Understanding and using the keyboard, screen and menu sequence.
- Acquiring and storing ECG.
- Maintenance

System Description

The VX3+ ANS recorder is a portable, battery-operated ANS recorder used by trained technicians to collect ECG data from patients in a clinical, point-of-care or outpatient setting. Data is recorded to a Secure Digital (SD) card and then transferred to a ANS system for review by a physician or other qualified professional.



Fig 1.1 VX3+ Holter recorder (Front)

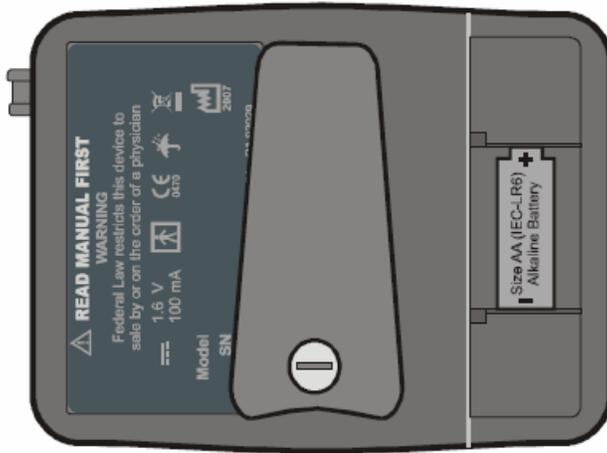


Fig 1.2 VX3+ Holter recorder (Back)
(Battery Compartment Cover Removed)

Section 2: Getting Started

A Secure Digital (SD) card and a battery must be installed to operate the VX3+. The SD card must be installed before the battery is installed.

Secure Digital (SD) Card

The VX3+ stores acquired ECG data to a standard SD card with capacity between 128mb and 2GB. Industrial style SD cards are suggested. To insert the SD card, remove the battery cover on the back of the recorder and insert the card face up as shown in *Fig 2.1*. Push it into the slot until it clicks into place. To remove the SD card, push the card into the slot and it will release. You can then pull the card out of the slot. The battery must be removed prior to inserting or removing the SD card.



Fig 2.1 Secure Digital Card Placement

Battery

The VX3+ uses one alkaline AA battery (IEC-LR6). No other batteries may be used. To install the battery, remove the battery door on the back of the device, and place as shown on the placement reference molded on the inside of the battery compartment. If a battery has power, but is too weak to run a 24-hour study, the recorder will beep continuously and display a low battery warning. The VX3+ monitors battery voltages during a study. It will run until the charge falls below an acceptable level. When this occurs the VX3+ will shut down.

Note: A loss of up to 2 minutes data may occur if the battery is removed during a recording.

NOTE: If the VX3+ will not be in use for a prolonged period of time, remove the battery from the device.



Caution: INSERT BATTERY AS DIRECTED IN THIS MANUAL. IMPROPER INSTALLATION COULD DAMAGE THE DEVICE AND IMPACT THE DEVICE'S ABILITY TO PERFORM THE PATIENT'S ECG TEST.



Caution: THE BATTERIES USED IN THIS DEVICE MAY PRESENT A FIRE OR CHEMICAL BURN HAZARD IF MISTREATED. DO NOT DISASSEMBLE, HEAT ABOVE 100° C (212° F) OR INCINERATE.



Caution: KEEP THE BATTERY COMPARTMENT DRY. DO NOT IMMERSE IN WATER. DISPOSE OF ALL BATTERIES PROPERLY. DO NOT DISPOSE IN TRASH. KEEP AWAY FROM CHILDREN.

Screen Navigation

The VX3+ use various menus to set preferences and enter patient information. Four keys, left, right, up and down, are used to navigate the menus. The enter key is used to make a selection of a highlighted item.



Fig 2.2 Navigation Keys

Selecting Features and Preferences

Start Up

Upon insertion of a battery, the VX3+ performs a system check and briefly displays the splash screen. The device serial number and firmware version are shown on the splash screen. The next screen to appear is the Setup Menu. Recording parameters and preferences are selected with the Setup menu. Press the Right Arrow key to exit the Setup menu and proceed with a recording.

Note: Unless modified, Sample Rate, Recording Length, Date Format and Time Format will default to the previous session's settings.

Upon leaving the Setup Menu, the VX3+ will prepare the SD card for recording and then enter the ECG display screen. The ECG display screen can be used to evaluate the patient hook-up. Pressing the enter key will cycle the ECG display between three channels of ECG and each of the three channels of ECG individually. The recorder will enter recording mode automatically in approximately eight minutes. Press and hold the enter key for four seconds to immediately enter record mode from the ECG display screen.

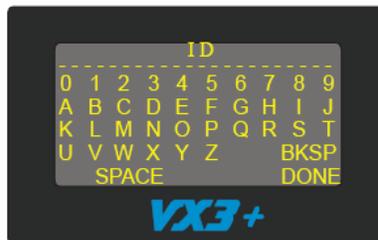
Setup Menu

The Setup menu is used to set device preferences, time, date and enter patient information if desired. The following items can be selected on the setup menu:

- 1) Set ID
- 2) Set Name
- 3) Pacemaker
- 4) Sample Rate
- 5) Record Length
- 6) Set Time
- 7) Set Date
- 8) Preferences

Set ID

Set ID is selected to enter a Patient Identification number. The navigation keys are used to navigate the character screen. Once a character is highlighted it can be selected with the enter key. After patient ID is entered, select DONE and press enter to return to Setup menu.



Set Name

Set Name is used to enter a patient name. The navigation keys are used to navigate the character screen. Once a character is highlighted it can be selected with the enter key. After patient name is entered, select DONE and press enter to return to Setup menu.

Pacemaker

The VX3+ is designed to detect pulses generated by pacemakers. The recorder will detect signals from .1 ms to 2 ms that have rise times faster than or equal to 100 microseconds and amplitudes between +-2 mV and +-500 mV. Pacemaker annotations are made if the signal is detected on at least two channels. The pacemaker setting allows pacemaker detection to be set to either on or off. The default is off for the ANS test.

NOTE: Patient lead placement and preparation are important factors to maximize accuracy of pace pulse detection. Noise with the above characteristics may be detected as pace pulse occurrences.

Sample Rate

Use the listings under sample rate to select desired ECG sampling rate. Sample rates of 128, 256, 512 and 1024 samples per second (sps) can be selected. Choose only sample rates supported by your particular ANS playback system. Sample rate defaults to previous recording session's sample rate.

Note: Sample rate choice for the ANS test is typically 256 samples per second (sps).

Record Length

Record length is used to select desired recording time. The choices are 24, 48, 72 and 96 Hrs. Sample rate, battery life and SD card size may affect maximum recording length. If a selected recording length is too long for the SD card size and selected sample rate the VX3+ will display a warning message.

Note: The ANS test is short and the record length is not a factor.

Real Time Clock

The time is set from the Set Time menu. The time can be displayed in either 12-hour or 24-hour format. The time display preference is selected from the preferences menu. The current time flashes on the display screen approximately every four seconds during recording. The date is set from the Set Date menu. The date can be displayed in MM/DD/YY or DD/MM/YY format. The display format is selected from the preferences menu.

Attaching Recorder to Patient

Patient Cable

The Patient cable connects to a port on the left side of the VX3+. The cable can only be inserted in one direction, and will easily snap into place when properly positioned. Do not force a cable into position. Both a 5-lead 3-Channel patient cable (part # 850-05R1-100) and a 7-lead 3-channel patient cable (part # 850-07R1-100) are available.

Patient Preparation

Note: Proper patient preparation and electrode placement are important for acquiring a high quality ECG.

1. Prepare the electrode site by removing oils, and lotion from the skin. If necessary, shave the area where electrodes will be placed.
2. Clean the skin at the placement site with an alcohol prep pad.
3. Dry the area with a lint-free cloth.
4. Use Silver Chloride disposable electrodes designed for 24 hour monitoring. Do not use 12-lead ECG or Stress Test Electrodes.

Estimated Maximum Run Time in Hours.				
Sample rate	SD card size			
	128MB	256MB	512MB	1GB
128 sps	69	72	96	96
256 sps	34	69	72	72
512 sps	17	34	48	48
1024 sps	8	17	24	24

Fig 2.4

Patient Hookup

In order to obtain a high-quality ECG signal it is necessary to maintain good electrical contact between the electrodes, patient cables and the patient's skin. Suggested electrode placements are shown in the diagrams below in *Figures 2.5 and 2.6*. However, it is up to the physician to make the final placement determination. The recorder's ECG display screen can be used to verify a proper patient hookup.



Warning: DO NOT RELY ON THE LED DISPLAY AS A DIAGNOSTIC TOOL.

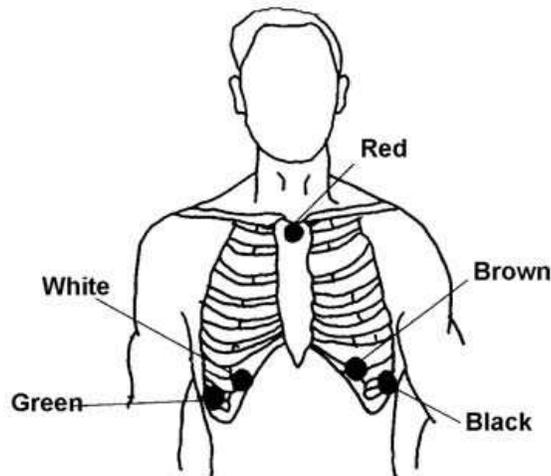


Fig 2.5 5-Lead 3-Channel Electrode Placement

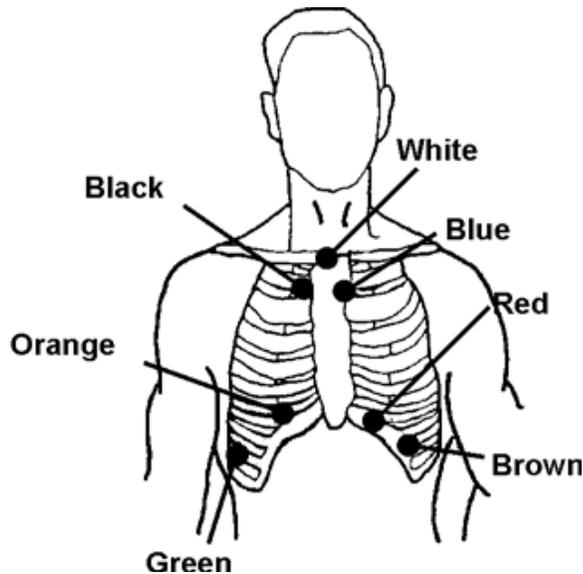


Fig 2.6 7-Lead 3-Channel Electrode Placement

Read and follow instructions included with the electrodes.

1. Check the patient cable for damage or wear. Replace if necessary. Use Silver Chloride disposable electrodes designed for 24 hour monitoring.
2. Place the electrodes onto the ECG leads.
3. Remove the backing from the pre-gelled disposable electrode.
4. Firmly place an electrode on each of the prepared skin surface sites. Dispose of any electrode that does not properly adhere to the skin.

Section 3: Recording an ANS ECG

Data File Check

Once the battery is inserted, you will hear a “beep”, and the Splash screen will appear. The Splash screen displays the revision of the firmware for the recorder. Depending on the version of recorder, a Data File Check screen may appear. This is a warning indicating the previously recorded ECG data file has not been played back in a ANS system. Either remove the SD card and download the file into the ANS system or press the enter key to erase the file and continue to the Setup screen

The Setup screen is the next screen displayed. Follow the instructions in Section 2 to modify settings or press the right arrow key to proceed to the ECG display screen.

Note: Unless modified, Sample Rate, Recording Length, Date Format and Time Format settings will default to the previous session’s settings.

The ECG display screen can be used to evaluate the patient hook-up. Pressing the enter key will cycle the ECG display between three channels of ECG and each of the three channels of ECG individually. The recorder will enter recording mode automatically in approximately eight minutes. Press and hold the enter key for four seconds to immediately enter record mode from the ECG display screen.

Event Button

All keys on the recorder will function as a patient event button during recording. Pressing the event button while recording will store a time stamp reference on the flash card.

Autonomic Nervous System Test Sequence

After pressing the Patient Event Button the recorder will complete its internal setup functions.

“Press Event Button to Start Paced Breathing Test” will appear on the Display.

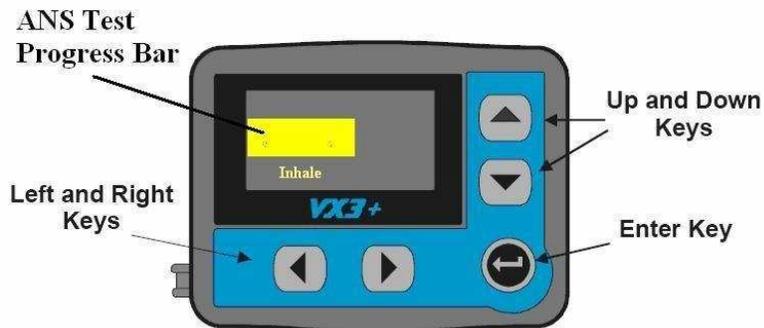
Event Button Pressed to start Paced Breathing Test

The Patient will now perform the Paced Breathing Exercise.

A bar will appear on the left of the display and move to the right. The message on the Display will be “INHALE” It will take 5 seconds for the bar to cross the display. After 5 seconds a beep will sound and the bar will again start to cross the display. The message on the Display will be “EXHALE”. It will take 5 seconds for the bar to cross the display. The Paced Breathing Test will be a series of 24 displays of a bar crossings of the Display. The displays will alternate between the messages “INHALE” and “EXHALE”. The total test time will be 120 seconds. After the test is complete the Display will say “Test Complete”. This message will be displayed for 3 seconds.



Figure 3.0 ANS Start the Paced Breathing Test





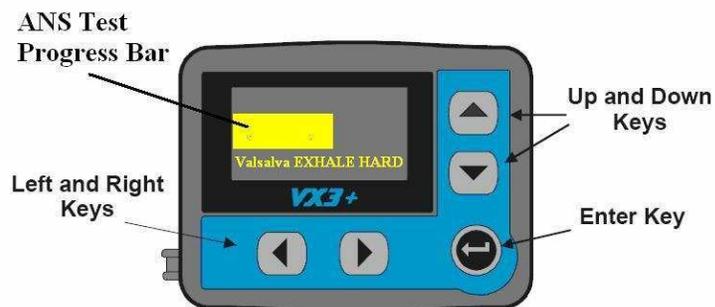
After the Paced Breathing test is complete and the 3 seconds have elapsed the Display will display “Press Event Button to start Valsalva Test”.

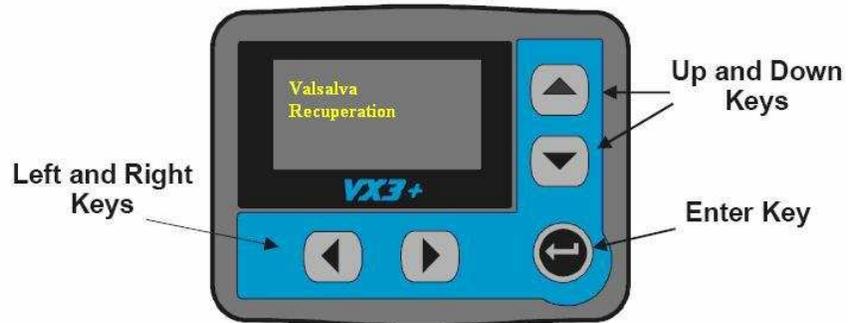
Event Button Pressed to start Valsalva Test.

The Patient will now perform the Valsalva Exercise.

A bar will appear on the left of the display and move to the left for a period of 20 seconds. The message on the Display will be “EXHALE HARD”. The total test time will be 20 seconds. After the test is complete the Display will say “Test Complete”. The “Test Complete” message will be displayed for 3 seconds.

When the Valsalva Test is complete the patient should breathe normally for a minimum of 1 minute (60 seconds). After the “Valsalva Complete” message has been displayed for 3 Seconds the display message will change from “Valsalva Complete” to “Valsalva Recuperation”. This is the recuperation from the Valsalva test. If the patient event button is pressed during the recuperation phase an error message will appear saying “Recuperation Phase NOT Complete” and the operator will not be allowed to continue for the 60 second recuperation phase.





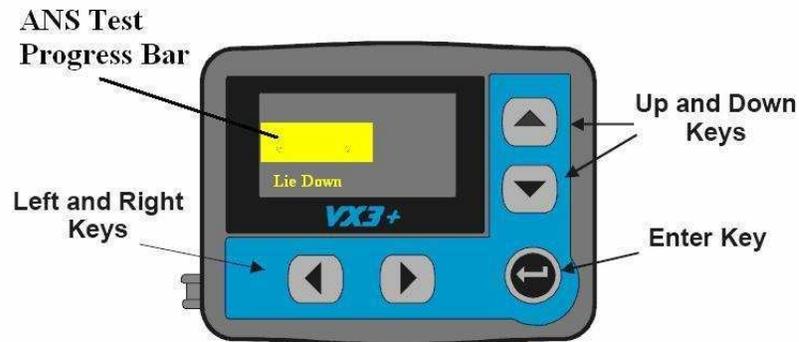
When Valsalva Recuperation is complete the patient should lie down to start the posture test. After the Valsalva Recuperation phase is complete the message on the display will be “Press Event Button when Patient lies down”.

Event Button pressed when Patient lies down

The Patient will now perform the Posture Exercise.

The message on the display will be “Lie Down”. A bar will move across the display during the 5 minute lying down phase. After the 5 minute period the display will say “Press Event button when Patient Stands”. If the patient event button is pressed during the 5 minute lying down phase an error message will appear saying “Posture Test NOT Complete”.

Event Button pressed when Patient stands up





After the patient stands up the system will count for a time of 30 seconds.

The display will say "ANS Test Complete"





Warning: REMOVING AND REPLACING THE BATTERY DURING A STUDY MAY RESULT IN THE LOSS OF ALL PATIENT DATA.

Data Retrieval

ECG data is stored on a SD card located in the battery compartment. To remove the SD card, push the card into the slot and it will release. You can then pull the card out of the slot. The ECG Data may now be placed into a card reader and loaded into the ANS software for analysis. Please refer to operating instructions for your ANS system.



Warning: ANS REPORTS MUST BE READ BY A PHYSICIAN WHO IS TRAINED TO INTERPRET AN ANS STUDY. PHYSICIANS SHOULD ORDER A REPEAT STUDY WHEN THE ANS IS OF POOR QUALITY.

Recorder Messages

There are several messages that could appear to alert you that action may be required before proceeding, or simply to alert you that an error has occurred. These messages include:

MESSAGE	POSSIBLE CAUSE	ACTION
Low Battery	Low Battery or rechargeable battery inserted	Replace battery
SD card not inserted	SD card not fully inserted / Bad SD card	Insert SD card fully into recorder / If fully inserted, replace SD card
Data file has not been read	Previous data file has not been reviewed in Holter system / Holter system did not flag data file as read	Press enter to ignore and continue or load data into Holter system
SD card error	Bad SD card or non-compatible SD card	Replace card
Warning Patient cable has not been detected	Patient cable not inserted	Insert patient cable
Error SD card is too slow for selected sample rate	Low performance or SD card in deteriorating condition	Replace SD card. Industrial style suggested.
Warning SD capacity is too small for sample rate and record length	Chosen sample rate and record length exceed SD card size	Insert larger SD card or reduce either sample rate or record length.

Section 4: Device Maintenance

Inspection and Cleaning

Routine inspection will help maintain the safety and performance of your VX3+ ANS recorder. Before operating the device perform a visual inspection to identify any worn, broken or missing parts, and repair or replace as necessary.

The outside surfaces can be cleaned with a mild soap and water solution.

Do not dispose of unit in trash. Dispose of as the Waste Electrical and Electronic Equipment (WEEE) regulations for your area require.



Caution: DO NOT IMMERSE THE DEVICE IN LIQUID!



Caution: DO NOT CLEAN THE PATIENT CABLES WITH ALCOHOL. DO NOT AUTOCLAVE THEM, OR USE ULTRASONIC CLEANERS.



Caution: DO NOT USE ANY HARSH CHEMICALS SUCH AS ACETONE, CHLORINE BLEACH, AMMONIA, OR IODINE TO CLEAN THE VX3+.

Testing

The VX3+ executes a power-on self check when the battery is inserted. Any errors in the unit's subsystems will be reported with an appropriate error message. Following the instructions on the screen and then removing and replacing the battery can remedy most errors. A blank display indicates a discharged battery or a malfunctioning device. If error messages persist contact your CAIRD TECHNOLOGY INC. service representative. Except for battery and SD card replacement, there are no user serviceable parts in the VX3+. The unit must be returned to CAIRD TECHNOLOGY INC. for service. The VX3+ may also be tested by attaching the patient leads to a commercially available ECG simulator and verifying each lead has amplitude and morphology as described in the simulator's manual. Excessive artifact usually indicates the patient cable needs replacing. Use only replacement cables purchased from CAIRD TECHNOLOGY INC..

Battery Maintenance and Precautions

Use only AA Alkaline Batteries (IEC-LR6). Use of another battery may present a risk of short recordings, device damage, or malfunction. Remove batteries from VX3+ unit promptly when depleted. Never store a battery in the recorder.



Caution: KEEP THE BATTERY COMPARTMENT DRY. DO NOT IMMERSE IN WATER. DISPOSE OF ALL BATTERIES PROPERLY. DO NOT DISPOSE IN TRASH. KEEP AWAY FROM CHILDREN.

VX3+ SPECIFICATIONS

Physical:

Dimensions	3.45" x 2.6" (88MM X 66MM)
Enclosure	ABS+PC, IPX0
Weight	2.7 ounces, 76.6 grams
Operating Position	Any Orientation
Operating Temperature	0 – 40 degrees C
Storage Temperature	0 – 70 degrees C
Operating Humidity	10 – 90% (non-condensing)
Storage Media	Removable Secure Digital card (128MB-2GB)
Batteries	AA Alkaline Batteries (IEC-LR6)

Functional:

Operating Duration	Programmable
Channels	3 Channels
Input Leads	5 or 7
Sample Rate	128 – 1024 Hz
Input Range	10 mV
CMRR	>60 dB
Key Panel	5 keys (Up, Down, Right, Left, Enter)
SD card Capacity	128 MB to 2 GB
Real Time Clock	1/10 Second Resolution

The VX3 is compliant with IEC 60601-1 as a Type BF, internally powered device designed for short time operation. The equipment is not suitable for AP or APG category environments.

Service/Technical Support:

205 Camden Chase
Columbia, South Carolina
29223
Tel: 803-237-8175



Warning: THE USE OF ACCESSORIES AND CABLES OTHER THAN THOSE SPECIFIED MAY RESULT IN INCREASED EMISSIONS OR DECREASED IMMUNITY OF THE VX3+.



Warning: THE VX3+ SHOULD NOT BE USED ADJACENT TO OR STACKED WITH OTHER EQUIPMENT. IF ADJACENT OR STACKED USE IS NECESSARY, THE VX3+ SHOULD BE OBSERVED TO VERIFY NORMAL OPERATION IN THE CONFIGURATION IN WHICH IT WILL BE USED.

Emissions test Compliance Electromagnetic environment - guidance

Guidance and manufacturer's declaration - electromagnetic emissions		
The VX3+ is intended for use in the electromagnetic environment specified below. The customer or user of the VX3+ should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR11	Group 1	The VX3+ uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class B	The VX3+ is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions CISPR11	N/A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A	

Guidance and manufacturer's declaration - electromagnetic immunity			
The VX3+ is intended for use in the electromagnetic environment specified below. The customer or user of the VX3+ should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the VX3+, including cables, than the recommended separation distance calculated for the equation applicable to the frequency of the transmitter. Recommended separation distance. $d = 1.17\sqrt{P}$
Radiated RF IEC 6100-4-3	3 V/m 80 MHz to 2.5 GHz	3V/m 80 MHz to 6.0 GHz	$d = 1.17\sqrt{P}$ 80 MHz to 800 MHz $d = 2.33\sqrt{P}$ 800 MHz to 6.0 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level on each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
^a Field strengths from fixed transmitters such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To access the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the VX3+ is used exceeds the applicable RF compliance level above, the VX3+ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the VX3+.			
^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The VX3+ is intended for use in the electromagnetic environment specified below. The customer or user of the VX3+ should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV air	+/- 6 kV contact +/- 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	N/A	N/A
Surge IEC 6100-4-5	+/- 1kV line(s) to lines(s) +/- 2kV line(s) to earth	N/A	N/A
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	N/A	N/A
Power frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic if a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level			

Recommended separation distances between portable and mobile RF communications equipment and the VX3+			
The VX3+ is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the VX3+ can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the VX3+ as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 5 GHz $d = 2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.77
1	1.17	1.17	2.33
10	3.69	3.69	7.37
100	11.67	11.67	23.3
<p>For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.</p> <p>NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			